

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

NOVARTIS'S MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Federal Rule of Civil Procedure 65, Plaintiff Novartis Pharmaceuticals Corporation seeks a preliminary injunction to enjoin the enforcement of H.B. 1065, a recently enacted Maryland law, which becomes effective on **July 1, 2024**. *See* 2024 Md. Laws ch. 962 (H.B. 1056 & S.B. 986 (2024)).¹

H.B. 1056 requires manufacturers to provide the federal 340B drug discount on an unlimited number of transactions involving for-profit pharmacies (known as “contract pharmacies”). The law purports not only to enforce the federal 340B laws but also to substantially expand the obligations imposed on drug manufacturers under the federal 340B statute. Maryland’s law is unconstitutional, for several reasons.

¹ Available at <https://mgaleg.maryland.gov/2024RS/bills/hb/hb1056T.pdf>.

First, H.B. 1056 directly conflicts with Congress's carefully enacted federal 340B statute, which requires drug manufacturers to provide deeply discounted prices on their covered outpatient drugs to qualifying "covered entities"—hospitals and clinics meeting specified statutory criteria. 42 U.S.C. § 256b. In implementing the federal 340B Program, Congress detailed 15 specific types of "covered entities" that qualify for discounts on manufacturers' outpatient drugs. For-profit pharmacy chains are not on that list. For that reason, four federal courts (including the D.C. Circuit and the Third Circuit) have held that federal 340B law does *not* require manufacturers to recognize an unlimited number of contract pharmacies. But that is precisely what Maryland's H.B. 1056 purports to mandate, greatly expanding the scope of 340B discounts in conflict with federal law.

H.B. 1056 further conflicts with the federal 340B enforcement process by purporting to create its own state-level 340B enforcement mechanism. Congress gave no authority to the States to administer, interpret, or enforce any aspect of the 340B Program. Yet H.B. 1056 purports to do exactly that.

Maryland's H.B. 1056 also is preempted by federal drug laws, including the Food, Drug, and Cosmetic Act (FDCA) and federal patent laws.

Finally, Maryland's H.B. 1056 violates the dormant Commerce Clause by fueling an economically protectionist regime. The state law unlawfully regulates wholly out-of-state transactions between manufacturers and wholesalers, and it does so with both discriminatory intent and discriminatory effect. It also privileges in-state pharmacies' economic interests at the expense of out-of-state manufacturers.

The four factors governing injunctive relief strongly favor issuance of an injunction here. Novartis's likelihood of success is strong. And absent immediate judicial intervention enjoining H.B. 1056, Novartis will suffer irreparable harm. Once the law becomes effective on July 1, 2024,

Novartis will risk violating Maryland law merely by continuing to implement a contract pharmacy policy that has already been declared lawful by other federal courts applying the federal 340B law. Novartis also faces the imminent threat of unconstitutional state administrative proceedings and draconian civil and criminal penalties—none of which are permitted under federal law. And because neither federal law nor state law provides any clear mechanism for Novartis to recover the state-mandated discounts once given, all of the losses from the unlawfully mandated discounts—amounting potentially to millions of dollars—would be irrecoverable.

In contrast, the State of Maryland faces no harm if preliminary injunctive relief is granted because the only loss facing the State is a temporary delay in any enforcement action. Patients also would not be harmed by an injunction. Patients typically do not receive the benefit of 340B discounts; the financial benefit more commonly accrues to covered entities and their contract pharmacies, and there is no federal or state requirement that the savings be spent on patient-specific pursuits.

Counsel for Novartis contacted counsel for the Attorney General's office on Tuesday, May 28, 2024 to advise them that Novartis would be filing this motion. Counsel for Novartis will provide courtesy copies of relevant filings to the Attorney General's office and will seek to negotiate a joint briefing schedule with the Attorney General's office after filing this motion.

For these reasons and those provided in its accompanying memorandum, Novartis moves for a preliminary injunction enjoining the enforcement of H.B. 1056 pending a decision on the merits. A proposed order accompanies this motion. Novartis respectfully requests a hearing on this motion.

Respectfully submitted,

/s/ Susan M. Cook
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**Pro Hac Vice Motion Forthcoming*

***Application for Admission Forthcoming*

*Attorneys for Novartis Pharmaceuticals
Corporation*

Dated: May 29, 2024

CERTIFICATE OF SERVICE

I hereby certify that on May 29, 2024, I electronically filed this motion with the Clerk of Court for the United States District Court for Maryland using CM/ECF. The motion along with the accompanying memorandum, exhibits, and proposed order will be served along with the Complaint by process server on the following:

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Board President
Maryland Board of Pharmacy
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/s/ Susan M. Cook

Susan M. Cook

Dated: May 29, 2024